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UNCLAS SECTION 01 OF 04 WARSAW 001122

SIPDIS

E.O. 12958: N/A

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SUBJECT: Poland: 2005 Special 301 Submission - Gradual Progress in Fighting Piracy and Improving IPR Protection

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Summary

1. (SBU) Poland's efforts to improve its IPR protection continued through the fourth quarter of 2004, with increased activities by customs and police authorities to curb IPR violations in the optical disc area. It is clear that copyright and trademark protection is significantly better than several years ago. Since May 1, 2004, Poland also has doubled its period of pharmaceutical data protection to six years to meet EU requirements. Progress on other pharmaceutical IPR issues is less pronounced, with Poland still lacking official linkage between Polish patent authorities and offices responsible for drug registration and market approval. Although U.S. industry has reported no new infringing generics making their way on to the reimbursement list since last year's out-of-cycle review, one major U.S. research pharmaceutical firm is concerned marketing approval may soon be granted to a generic version of one of its blockbuster drugs.

2. (U) In a major new market access development, the U.S. generics drug manufacturer Ivax has taken over Polfa Kutno, one of Poland's largest generics drug companies. The takeover gives the U.S. firm a major share of the Polish generics market for the first time. In addition, a U.S. logistics firm UTT, which specializes in the direct shipment of drugs from manufacturers to pharmacies and hospitals, started operations in Poland in January 2005. The firm offers services designed to allow drug manufacturers and Poland's independent pharmacies to entirely bypass the current wholesale distribution system, which is dominated by a handful of wholesalers. The move was warmly welcomed by the Polish Association of Pharmacies. Finally, although we still have no confirmation of this (and likely will not until March), Health Ministry officials have stated that new innovative drugs will be on the public health system's revised reimbursement list due out in March 2005. The move would break a de facto moratorium in effect since 1998.

3.(SBU) Taking into account the progress Poland has made in copyrights and trademarks, and distance it still has to go to adequately protect pharmaceutical property, the Embassy recommends that the country remain on the Watch List.

OD Piracy Efforts

4.(SBU) As reported in reftel C, Polish authorities have targeted Warsaw Stadium and bazaars along the Polish-German border for increased OD investigations. In a major development, two illegal CD production facilities supplying Warsaw Stadium were identified and closed. To demonstrate their commitment to stamping out piracy, Polish police authorities have for the first time invited the Embassy's trade officer to accompany them on an upcoming raid on a provincial open air market where pirated CD's and other goods (primarily liquor and apparel) are trafficked. Police continue to work closely with industry representatives to coordinate enforcement efforts.

Other Anti-piracy Actions

5. (U) In the last quarter of 2004, police officers from Warszawa-Praga Poludnie Division apprehended 35 suspects for piracy, and on the basis of secured evidence, initiated 30 criminal proceedings (although trials have not yet begun). Merchandise confiscated in these arrests included:

CD	16,481
CD-R	3,619
DVD	5,808
MP-3	522
Play-Station	665

The estimated total value of these seizures is about \$607,000.

6. (U) In addition, during the fourth quarter of 2004,

Polish courts also started eight criminal proceedings involving eight suspects for which the following evidence has been seized:

CD	26,650
CD-R	2,317
DVD	13,176
MP-3	201
Play-Station	533

The estimated total value of these seizures is approximately \$1.03 million.

Official Reporting and OD Law Compliance

7.(U) The Union of Producers of Audio Video (ZPAV), the International Federation of the Phonographic Industry (IFPI) representative office in Poland, reports that a number of anti-piracy activities have been undertaken after the amendments to the Law on Copyright and Neighbouring Rights and a Decree of the Ministry of Culture on conducting inspections by authorised employees came into effect.

8.(U) The Legal Department of the Ministry of Culture has officially notified various OD plants about new reporting obligations stemming from the amended law and a Ministerial decree. These will require factories to submit information about the production of optical discs and any movement of pressing equipment and accessories.

9.(U) Inspectors from the Ministry of Culture, authorized by the Legal Department of the Ministry, conducted formal inspections of five OD plants. Inspectors prepared reports of their activities and documented collected samples. Inspection reports together with recommendations for further action were forwarded to all inspected entities. ZPAV prepared inspectors of the Ministry of Culture for these inspections by providing the Ministry with a database for storing information required in Ministerial Decree. ZPAV representatives also participated in inspections of selected CD plants.

Pharmaceuticals IPR Protection

10.(SBU) Pharmaceutical industry complaints over the last several years have focused largely on two patent-infringing generics that have been given marketing approval several years ago and placed on the reimbursement list. In one case, the Polish courts subsequently upheld the rights of the U.S. manufacturer and ordered the competing product removed from the market (the foreign competitor is appealing the verdict). In the second example, the U.S. company lost its case in the lower courts and is appealing the case. (Note: The same U.S. firm appears to have lost a patent case in the United States involving the same product against a U.S. generics producer in 2003.)

11.(SBU) These cases have been reported in previous Special 301 reviews as a major obstacle for the innovative pharmaceutical industry in Poland. We share these concerns with industry, and have reinforced the message that market approval and placement on the reimbursement list for infringing generics is a serious IPR violation. However, we have no knowledge of any new patent violations over the past year, echoing our finding in the 2004 out of cycle review. Nevertheless, one major U.S. drug-maker is concerned that Polish authorities may soon grant marketing approval for a copy of one of its signature drugs may soon be given. The particular drug is protected by a process patent in Poland, and the U.S. company fears that a local competitor will obtain marketing approval for an alternative manufacturing process for the active ingredient without doing all of the detailed clinical work and certifications required of the U.S. manufacturer during its original submission. The U.S. firm confirms, however, that the copy has not yet appeared on the market as of late February 2005. Finally, we note that since May 1, 2004, Poland has adopted the six-year EU standard for data protection, effectively doubling the period of protection.

Pharmaceutical Market Access

12.(U) The Polish national health system's official reimbursement list, which effectively accounts for an estimated 60 percent of the \$4.5 billion annual drug market in Poland, has not included an innovative drug since 1998. This is a major concern for U.S. manufacturers who feel that their new products are unfairly denied market access. (The Polish government argues that the Health system's budgetary crisis is the only reason for the freeze on newer, more

costly products.) We have learned that the Ministry of Health recently circulated for public consideration a draft reimbursement list, which will close for comment on February 21. The final official list is expected to be announced in early March.

13.(U) As of the February 9 Legal Affairs Working Group (LAWG) meeting of the AmCham in Warsaw (the group that represents pharmaceutical companies), U.S. firms indicated that they have no information regarding the presence of any new patent-infringing products on the proposed reimbursement list. While the comment period is still open, we find industry's silence on this issue telling. The Polish Health Ministry maintains that some new innovative drugs will be on the list. If confirmed, the move would represent the end of the de facto moratorium on listings for innovative drugs in effect since 1998.

14.(U) Finally, perhaps the biggest new development in the area of market access has been the entry into Poland of the U.S. Miami-based generic drugs and veterinary products manufacturer Ivax. On October 22, the Board of Governors of the Warsaw Stock Exchange approved Ivax's application for a listing on the Warsaw Stock Exchange (WSE). In November, the U.S. firm became the first American company listed on the Warsaw Stock Exchange, when it acquired a majority of the shares of one of Poland's largest generic drugmakers, Polfa Kutno. Ivax has now replaced Polfa-Kutno's listing on the exchange. The takeover--which valued Polfa-Kutno at around \$160 million-- gives the U.S. firm a significant share of the Polish generics market and represents the largest U.S. direct investment in drug manufacturing to date in the Polish market.

15. (U) On the distribution side, the U.S. firm UTI--a logistics firm specializing in, among other things, the direct shipment of pharmaceuticals to pharmacies and hospitals--recently started operations in Poland. The U.S. firm plans to create a logistics network that will allow pharmaceutical firms to bypass Poland's current distributions system, which is dominated by a handful of wholesalers. The set up of the operation was welcomed by Poland's Association of Pharmacies whose members have been under increasing pressure from wholesaler-operated chains.

Intel Trademark Infringement

16.(U) In reviewing the Intel submission, post notes that none of the problems mentioned appear to be current. The complaints seem to concern events which took place several years ago and which were resolved -- after some trouble and expense - in Intel's favor by 2003. As far as we are aware, Intel has not come to the embassy with any complaints since at least mid-2003. We are therefore uninformed about any more recent trademark infringement issues that the firm may have in Poland. However, if these exist, we would recommend that the firm would inform us of them.

17.(U) The main remedy Intel seeks seems to be reform of Poland's court system. The desire to make Poland's legal system more honest and efficient in all respects is a goal shared by the U.S. Embassy, the American Chamber of Commerce in Poland, and the local Polish business community. The World Bank has noted that Polish firms have great problems enforcing even routine financial contracts in the court system - a process which can take up to four years. Reform of the court system is a long-standing politically complex issue. However, it is difficult to regard this problem as fundamentally an IPR or market access issue.

Comment and Recommendation

18.(U) Poland continues to make clear measurable progress in improving IPR protection of optical discs. Over the past six months, the Culture Ministry has made efforts to inform OD producers of their reporting obligations and sensitize police authorities on the need for strict enforcement of IPR laws. To our knowledge, Poland is the only EU country with an OD law. For their part, the Polish Police appear to be making more serious efforts to break up rings trafficking in pirated merchandise and shut down open-air trade, including a major case involving FBI cooperation.

19.(U) In the area of pharmaceuticals, progress has been less noteworthy. While no new patent-infringing drugs have appeared on the market, there continues to be a lack of formal coordination between the Ministry of Health and the Patent Office. Thus U.S. research pharmaceutical firms continue to lack certainty that protection of their intellectual property will be upheld in each case. On the positive side, Poland has now lengthened the period of data protection to six years. It appears about to break its six-

year moratorium on placing innovative drugs on the reimbursement list. It has welcomed the acquisition of a major Polish drug firm by the U.S. generics firm Ivax. The Polish Association of Independent Pharmacies is enthusiastic about the recent opening of UTI's direct distribution channel in Poland. The presence of US firms on the Polish pharmaceutical market is expanding.

120. Taking into account the progress Poland has made and the distance it still has to go to adequately protect pharmaceutical property, the Embassy recommends that the country remain on the Watch List.